

**Complete Listing of Claims:**

This listing of claims will replace all prior versions, and listings, of claims in this application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

Claims 1 – 150. (Cancelled).

Claim 151. (Currently Amended) A pharmaceutical composition, comprising: omeprazole ~~a therapeutically effective amount of at least one acid labile substituted benzimidazole  $H^+$ ,  $K^+$ -ATPase proton pump inhibitor~~ and at least one buffering agent in an amount of about 0.05 mEq to about 5 mEq per mg of proton pump inhibitor, wherein:

- (a) the composition is in a form of a powder for suspension that is storage stable at room temperature; and
- (b) after mixing the powder with a liquid medium to form a suspension and orally administering the suspension to a group of subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~the proton pump inhibitor~~ of at least about 0.1  $\mu\text{g/ml}$  at any time within about 30 minutes after administration.

Claim 152. (Currently Amended) The composition of claim 151, wherein the ~~at least one proton pump inhibitor is selected from the group consisting of~~ omeprazole ~~is omeprazole or lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, lémnoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.~~

Claim 153. (Currently Amended) The composition of claim 152, wherein the omeprazole ~~at least one proton pump inhibitor~~ is present in the composition in an amount of about 1 mg to about 1000 mg.

Claim 154. (Currently Amended) The composition of claim 152, wherein the omeprazole ~~at least one proton pump inhibitor~~ is present in the composition in an amount of about 5 mg to about 300 mg.

Claim 155. (Currently Amended) The composition of claim 152, wherein the omeprazole ~~at least one proton pump inhibitor~~ is present in the composition in an amount of about 10 mg to about 100 mg.

Claim 156. (Currently Amended) The composition of claim 152, wherein the omeprazole ~~at least one proton pump inhibitor~~ is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35, about 40 mg, about 45, about 50 mg, about 55, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110mg, about 115 mg, about 120 mg, about 150 mg, about 200 mg, about 250 mg, or about 300 mg.

Claim 157. (Currently Amended) The composition of claim 151[[2]], ~~wherein the at least one proton pump inhibitor is omeprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof~~ further comprising a suspending agent.

Claim 158. (Withdrawn) The composition of claim 152, wherein the at least one proton pump inhibitor is lansoprazole, or an enantiomer, isomer, tautomer, prodrug, free base, or salt thereof.

Claim 159. (Currently Amended) The composition of claim 152, wherein the ~~at least one proton pump inhibitor~~ omeprazole is omeprazole or esomeprazole, or an ~~enantiomer~~, isomer, tautomer, prodrug, free base, or salt thereof.

Claim 160. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is selected from the group consisting of a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, a sodium buffering agent, a bicarbonate salt of a Group IA metal, an alkaline earth metal buffering agent, an amino acid, an alkaline salt of an amino acid, and mixtures thereof.

Claim 161. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is selected from the group consisting of sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium

phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, potassium phosphate, sodium phosphate, and mixtures thereof.

Claim 162. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 1 mEq to about 200 mEq.

Claim 163. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 3 mEq to about 45 mEq.

Claim 164. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 4 mEq to about 100 mEq.

Claim 165. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 4 mEq to about 30 mEq.

Claim 166. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 10 mEq to about 70 mEq.

Claim 167. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 7 mEq to about 25 mEq.

Claim 168. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 10 mEq.

Claim 169. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 20 mEq.

Claim 170. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 40 mEq.

Claim 171. (Withdrawn) The composition of claim 151, further comprising at least one pharmaceutically acceptable excipient selected from the group consisting of a carrier, a binder, a suspending agent, a thickening agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, an isotonic agent, and mixtures thereof.

Claim 172. (Withdrawn) The composition of claim 171 wherein the at least one excipient is a suspending agent.

Claim 173. (Withdrawn) A liquid dosage form prepared by mixing the pharmaceutical composition of claim 151 with an aqueous vehicle.

Claim 174. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent comprises sodium bicarbonate.

Claim 175. (Previously Presented) The composition of claim 174 wherein the sodium bicarbonate is present in the composition in a total amount of about 250 mg to about 4000 mg.

Claim 176. (Previously Presented) The composition of claim 174 wherein the sodium bicarbonate is present in the composition in a total amount of about 1000 mg to about 1680 mg.

Claim 177. (Previously Presented) The composition of claim 174 wherein the sodium bicarbonate is present in the composition in a total amount of about 20 mEq.

Claim 178. (Currently Amended) The composition of claim 177 wherein the ~~at least one proton pump inhibitor is omeprazole and said omeprazole~~ is present in the composition in an amount of about 20 mg.

Claim 179. (Currently Amended) The composition of claim 177 wherein the ~~at least one proton pump inhibitor is omeprazole and said omeprazole~~ is present in the composition in an amount of about 40 mg.

Claim 180. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent comprises magnesium hydroxide.

Claim 181. (Previously Presented) The composition of claim 180, wherein the magnesium hydroxide is present in the composition in a total amount of about 12 mEq to about 24 mEq.

Claim 182. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent comprises a mixture of sodium bicarbonate and magnesium hydroxide.

Claim 183. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent comprises calcium carbonate.

Claim 184. (Previously Presented) The composition of claim 151, wherein the at least one buffering agent comprises a mixture of sodium bicarbonate and calcium carbonate.

Claim 185. (Currently Amended) The composition of claim 151, wherein at least a portion of the omeprazole ~~at least one proton pump inhibitor~~ is micronized.

Claim 186. (Previously Presented) The composition of claim 151, wherein at least a portion of the at least one buffering agent is micronized.

Claim 187. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at least about 0.1 µg/ml at any time within about 20 minutes after administration.

Claim 188. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 189. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at least about 0.1 µg/ml at any time within about 10 minutes after administration.

Claim 190. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at least about 0.2 µg/ml at any time within about 15 minutes after administration.

Claim 191. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at least about 0.1 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 6 hours after administration.

Claim 192. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at least about 0.15 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 1.5 hours after administration.

Claim 193. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average  $T_{\max}$  within about 1 hour after administration.

Claim 194. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average  $T_{\max}$  within about 30 minutes after administration.

Claim 195. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average  $T_{\max}$  within about 45 minutes after administration.

Claim 196. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to

a group of fasted adult human subjects, the subjects exhibit an average  $T_{\max}$  within about 15 minutes to about 45 minutes after administration.

Claim 197. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average  $C_{\max}$  of the proton pump inhibitor of about 1.0  $\mu\text{g/ml}$ .

Claim 198. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average  $C_{\max}$  of the proton pump inhibitor of between about 0.5  $\mu\text{g/ml}$  to about 1.7  $\mu\text{g/ml}$  after administration.

Claim 199. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of greater than about 1.0  $\mu\text{g/ml}$  at any time within about 20 minutes after administration.

Claim 200. (Previously Presented) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of greater than about 1.0  $\mu\text{g/ml}$  at any time within about 40 minutes after administration.

Claim 201. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average  $C_{\max}$  of the omeprazole ~~proton pump inhibitor~~ of between about 0.5  $\mu\text{g/ml}$  and 1.7  $\mu\text{g/ml}$  at any time within about 45 minutes after administration.

Claim 202. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of between about 0.3  $\mu\text{g/ml}$  and 1.2  $\mu\text{g/ml}$  at any time within about 10 minutes after administration.

Claim 203. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of between about 0.5 µg/ml and about 1.6 µg/ml at any time within about 15 minutes after administration.

Claim 204. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at about 0.4 µg/ml at any time within about 20 minutes after administration.

Claim 205. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of between about 0.7 µg/ml and 1.2 µg/ml at any time within about 30 minutes after administration.

Claim 206. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of the omeprazole ~~proton pump inhibitor~~ is determined from about 15 subjects.

Claim 207. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of the omeprazole ~~proton pump inhibitor~~ is determined from about 15 adult human subjects and is at least about 0.4 µg/ml at any time within about 30 minutes after administration.

Claim 208. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of omeprazole ~~proton pump inhibitor~~ is determined from about 10 adult human subjects and is at least about 0.7 µg/ml at any time within about 30 minutes after administration.



Claim 209. (Currently Amended) The composition of claim 151, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average plasma concentration of the omeprazole ~~proton pump inhibitor~~ is determined from about 10 adult human subjects and is at least about 0.4 µg/ml at any time within about 15 minutes after administration.

Claim 210. (Previously Presented) The composition of claim 151, wherein the composition comprises 40 mg of omeprazole and wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the average  $C_{max}$  is about 1.0 µg/ml.

Claim 211. (Withdrawn) A pharmaceutical composition, comprising: a therapeutically effective amount of at least one acid labile substituted benzimidazole H<sup>+</sup>, K<sup>+</sup>- ATPase proton pump inhibitor and at least about 10 mEq of buffering agent, wherein:

- (a) the composition is in a form of a powder for suspension that is storage stable at room temperature; and
- (b) after mixing the powder with a liquid medium to form a suspension and orally administering the suspension to a group of subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.4 µg/ml at any time within about 30 minutes after administration.

Claim 212. (Withdrawn) The composition of claim 211, wherein the at least one acid labile substituted benzimidazole H<sup>+</sup>, K<sup>+</sup>- ATPase proton pump inhibitor is omeprazole, or an enantiomer, isomer, tautomer, prodrug, free base, or salt thereof.

Claim 213. (Withdrawn) The composition of claim 211, wherein the omeprazole is present in an amount of about 20 mgs.

Claim 214. (Withdrawn) The composition of claim 211, wherein the omeprazole is present in an amount of about 40 mgs.

Claim 215. (Withdrawn) The composition of claim 211, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to a group of fasted adult human subjects, the subjects exhibit an average  $T_{max}$  within about 45 minutes after administration.

Claim 216. (Withdrawn) The composition of claim 215, wherein upon mixing the powder with a liquid vehicle to form a suspension and orally administering the suspension to each member of a group of fasted adult human subjects in an amount of the suspension corresponding to about 40 mg of omeprazole, the subjects exhibit an average  $C_{max}$  of at least about 1.0  $\mu\text{g/ml}$ .

Claim 217. (Withdrawn) The composition of claim 211, wherein upon mixing the powder with a liquid medium to form a suspension and orally administering the suspension to each member of a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 1.0  $\mu\text{g/ml}$  at any time within about 20 minutes after administration.

Claim 218. (Withdrawn) The composition of claim 211, wherein upon mixing the powder with a liquid medium to form a suspension and orally administering the suspension to each member of a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 1.0  $\mu\text{g/ml}$  at any time within about 40 minutes after administration.